

to an article of food if the Secretary has credible evidence or information indicating that an article of food presents a threat of serious health consequences or death to humans or animals. This provision excludes farms and restaurants and is subject to certain limitations including limitations to ensure the protection of trade secrets and confidential information.

Section 304 authorizes the Secretary to issue a regulation requiring maintenance of additional records that are needed to trace the source and chain of distribution of food, in order to address credible threats of serious adverse health consequences to humans or animals. This provision excludes restaurants and farms, and the Secretary is provided the authority to take into account the size of the business when imposing any record keeping requirements and tailor the requirements to accommodate burden and costs considerations for small businesses.

Section 304 authorizes the issuance of regulations to require the maintenance of so-called "chain of distribution" records that would enable the Secretary to trace the source and distribution of food in the event of a problem with food that presented a threat of serious adverse health consequences or death to humans or animals. This authority may not be used to require a business to maintain records regarding transactions or activities to which it was not a party. The Secretary has indicated that chain of distribution records that document the person from whom food was directly received, and to whom it was directly delivered, would sufficiently enable adequate tracing of the source and distribution of food.

This records access would not extend to the most commercially sensitive or confidential records, including recipes, financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales). This authority would not permit access to any records regarding employees, research or customers (other than shipment data). Nor does it permit access to marketing plans.

Under Section 304 the Secretary must take appropriate measures to prevent the unauthorized disclosure of trade secret or confidential information obtained by the Secretary pursuant to this section. The Secretary shall ensure that adequate procedures are in place to ensure agency personnel will not have access to records without a specific reason and need for such access, and that possession of all copies of records will be strictly controlled, and that detailed records regarding all handling and access to these records will be kept.

Section 305 requires all facilities (excluding farms) that manufacture, process, pack or hold food for consumption in the United States to file with the Secretary, and keep up to date, a registration that contains the identity and address of the facility and the general category of food manufactured, processed, packed or held at the facility. This section authorizes the Secretary to exempt certain retail establishments only if the Secretary determines that the registration of such facilities is not needed for effective enforcement. The purpose of registration under this section is to authorize the Secretary to compile an up-to-date list of relevant facilities to enable the Secretary to rapidly identify and contact potentially affected fa-

cilities in the context of an investigation of bioterrorism involving the food supply.

Enforcement of Section 305 would be delayed 180 days from the date of enactment, and this section requires the Secretary to take sufficient measures to notify and issue guidance within 60 days identifying facilities required to register. This section also requires the Secretary to promulgate adequate guidance, where needed, to enable facilities to determine whether and how to comply with these registration requirements. The Secretary is encouraged to utilize the notice and comment process as an appropriate method for notifying potential registrants of their obligation to register and to receive advice and assistance from registrants on how best to develop a registration system that is both workable and cost-effective. In many instances, additional steps may be needed since the notice and comment may not be adequate to inform small businesses and other importers who may not have the resources or capabilities to research and track federal regulatory notices in a timely manner prior to the expiration of the 180-day enforcement bar.

This section does not impose a registration fee, and calls for a one-time registration. In other words, once a facility is registered it will only have to amend its original registration in a timely manner to reflect any changes. This section also allows and encourages electronic registration to help reduce paperwork and reporting burden, but registration would also be permitted using a paper form. The Department should work in a cooperative manner with facilities in terms of their obligations to register, and should be reasonable in situations where facilities are making good faith efforts to comply.

Registration should be made as simple as possible (such as permitting both electronic and paper registration, as well as permitting a headquarters to register on behalf of all establishments of a company) and the Secretary shall promptly complete a rulemaking regarding exemption from registration requirements for various types of retail establishments. As part of this rulemaking the Secretary should look broadly at the various types of the food establishments in order to ascertain whether they should be exempted and shall exempt from registration those facilities that are not necessary to accomplish the purpose of this section. The Secretary should assure that implementation of this section does not unnecessarily disrupt the flow of commerce.

Section 306 requires the Secretary to promulgate a rule to provide for prior notice to the Secretary of food being offered for import. The prior notice is to occur between 24 and 72 hours before the article is offered for import. In circumstances where timely prior notice is not given, the article is to be held at the port until such notice is given and the Secretary, in no more than 24 hours, examines the notice and determines whether it is in accordance with the notice regulations. At that time, the Secretary must also determine whether there is in his possession any credible evidence or information indicating that such article presents a threat of serious adverse health consequences or death to humans or animals. This determination by the Secretary should not delay or unnecessarily disrupt the flow of commerce.

Section 306 is not intended as a limitation on the port of entry for an article of food. In some instances, such as inclement weather, routine shipping delays, or natural disasters, a shipment of food may arrive at a port of entry other than the anticipated port of entry provided on the notice. When such situations arise, arrival at a port other than the anticipated port should not be the sole basis for invalidating a notice that is otherwise in accordance with the regulations. Also, the importer of an article of food is required to provide information about the grower of the article of food, if that information is known to the importer at the time that prior notice is being provided in accordance with the regulations. This provision only requires the importer to provide any information he has in his possession at the time that prior notice is being provided. The Secretary shall closely coordinate this prior notice regulation with similar notifications that are required by the U.S. Customs Service with the goal of minimizing or eliminating unnecessary, multiple or redundant notifications.

PERSONAL EXPLANATION

HON. HAROLD E. FORD, JR.

OF TENNESSEE

IN THE HOUSE OF REPRESENTATIVES

Thursday, December 20, 2001

Mr. FORD. Mr. Speaker, regrettably, I was not present for the vote on final passage of H.R. 3529, the Economic Security and Worker Assistance Act, or the preceding motion to recommit.

Had I been present, I would have voted "Yea" on rollcall vote number 508, the motion to recommit, and "Nay" on rollcall vote 509 final passage of H.R. 3529.

UNITED STATES FOREST SERVICE AND FISH AND WILDLIFE SERVICE REPORTS

HON. GEORGE R. NETHERCUTT, JR.

OF WASHINGTON

IN THE HOUSE OF REPRESENTATIVES

Thursday, December 20, 2001

Mr. NETHERCUTT. Mr. Speaker, the recent published reports about the planting of false evidence by biologists with the United States Forest Service and the United States Fish and Wildlife Service are alarming.

An internal Forest Service investigation has found that the science of the habitat study had been skewed by seven government officials: three U.S. Forest Service employees, two U.S. Fish and Wildlife Service officials and two employees of the Washington Department of Fish and Wildlife.

These officials, according to published reports, planted three separate samples of Canadian lynx hair on rubbing posts used to identify existence of the creatures in the two national forests. Had the deception not been discovered, the government likely would have banned many forms of recreation and use of natural resources in the Gifford Pinchot National Forest and Wenatchee National Forest in Washington State. The restrictions would

have had a real-life devastating impact on the economy of Washington State.

Today I join with many of my colleagues in demanding that these employees, upon evidence of their guilt is established, be immediately terminated. It is unacceptable that these employees have simply been counseled for their planting of evidence. Federal employees should be held accountable for their actions—period.

Further, I support a complete review of the lynx study as well as a review of any other projects on which these employees may have worked. The integrity of these agencies and our future efforts to protect threatened and endangered species depends on these reviews. As a member of the Interior Appropriations Subcommittee, I intend to make sure that this kind of activity never happens again and that the agencies involved are not perpetrating a fraud on the American people. That is my highest responsibility.

BEST PHARMACEUTICALS FOR CHILDREN ACT

SPEECH OF

HON. BART STUPAK

OF MICHIGAN

IN THE HOUSE OF REPRESENTATIVES

Tuesday, December 18, 2001

Mr. STUPAK. Mr. Speaker, I rise tonight to urge Members to vote against the pediatric exclusivity bill, S. 1789. It is the product of a flawed negotiating process, a flawed legislative process, and a flawed regulatory process which was instituted back in 1997.

First approved in 1997, pediatric exclusivity granted drug companies an extra six-month extension on their patent if they would conduct a study to determine what the effects were on young people. The FDA sends a written request for a pediatric study to the drug company. Upon completion of the study, FDA grants a six month extension of the patent monopoly—the “pediatric exclusivity”—which the drug companies then use as a marketing tool to promote and increase the drug's sales.

What I find horrifying is the grant of exclusivity takes place after the drug company does its study but before anyone knows what is included in the results of the study. Nothing is said to the general public—which includes parents and pediatricians—or prescribing physicians about the safety, effectiveness, or dosage requirements. Under S. 1789, there is no requirement to change the labeling on the drug to reflect the changes that may be needed when the drug is dispensed to young people. There is no label to tell doctors, patients, and their families the proper dosage, or how to dispense or use the drug.

My argument has always been this: before you grant pediatric exclusivity to a pharmaceutical company and before this exclusivity is then marketed as being FDA approved for pediatric use, shouldn't you at least know what is the effect of the drug on young people?

Under current law—and this bill would extend current law after the study is completed, exclusivity is granted, but whether the drug helps or hurts young people remains a secret and is not disclosed to the doctors, patients,

and their families for an average of 9 months. Shouldn't this information get out to these people before they ingest this medicine?

I have a chart, which I have used on the floor before. It highlights the problems with S. 1789, which does not require labeling changes until 11 months after the drug is being used in the pediatric population. How many of you would give your child a drug and not know whether it helps or harms your child until 11 months later?

There have been 33 drugs granted pediatric exclusivity. Only 20 have been re-labeled to reflect the results of the pediatric study, and even those label changes have taken an average of 9 months.

For 9 months, doctors, patients, and their families have no idea if the child is receiving the proper dosage or even if the drug is really safe!

Now why can't doctors, patients, and their families know this information before the grant of pediatric exclusivity is given? I was not allowed a chance to offer my amendment before the full House. My amendment is very simple and very commonsense: before pediatric exclusivity is granted, all drugs must be labeled especially for pediatric use.

Under other prescription drug patent extension programs, labeling is an absolute prerequisite to receiving patent extension. But not pediatric exclusivity. Why would we treat our children any differently?

For the love of me, I cannot understand why the majority does not want doctors, patients, and their families to know the effect of drugs may have on children!

What is the proper dosage? What is the efficacy? What is the safety level for our children?

Why do we wait an average of 9 months before we see proper labeling? Why must we wait to find out if a child has received the proper dosage?

Let us defeat this legislation. I urge a no vote.

UNITED STATES SECURITY ACT

HON. JERRY F. COSTELLO

OF ILLINOIS

IN THE HOUSE OF REPRESENTATIVES

Thursday, December 20, 2001

Mr. COSTELLO. Mr. Speaker, I rise today in support of the Democratic Caucus' Homeland Security bill, the United States Security Act (USA Act).

This legislation is a collaborative effort crafted by my democratic colleagues on the Homeland Security Task Force. I was honored to have served as the vice chair of the Transportation Security task force with my friend, BOB BORSKI, who chaired the task force.

The USA Act addresses funding needs to improve our homeland security in the following areas: public health, transportation, physical and informational infrastructure, law enforcement and the military. As the attacks of the 11th clearly and unfortunately demonstrated, our nation is vulnerable to attack. This bill goes a long way to minimize those vulnerabilities.

In the past five years—and prior to the 11th—there have been international events

which highlighted potential weaknesses in our transportation systems. In Tokyo, Japan, individuals caused harm by releasing sarin gas in the subway system. The USGS *Cole* was attacked in a seaport that, although in Yemen, was considered safe. While these attacks occurred overseas, they could have taken place here in the States.

With the passage of the Aviation Security Act earlier this year, significant improvements to aviation security were mandated. However, other modes of transportation could still be susceptible to attack. This legislation authorizes funds to secure bridges, tunnels, dams, seaports, rail, and public transit.

Specifically, the bill provides \$3.6 billion to strengthen bridge and tunnel structures, improve inspection facilities and the inspection of Hazmat materials on highways, supply the traveling public with real-time information about availability roads and bridges if terrorist attacks were to occur again, and improve security for locks and dams. It also provides \$992 million to enhance security at our seaports by increasing coast guard personnel, establishing a sea marshal program, requiring transponders for foreign vessels in U.S. waters, and screening ship cargo by x-ray. To improve security on transit systems, \$3.2 billion is authorized. Funds would be used to hire additional security personnel, improve communications and refine mass transit evacuation plans. With the appropriation of funds, the security of these transportation systems will markedly improve.

The USA Act also authorizes funds to strengthen communities responses to emergency incidents. This is done by increasing the number of firefighters, providing grants to communities and first responders and improving technology so that important information can be more readily shared between local, state and federal governments. Our nation's first responders are an integral component in response to a terrorist attack, and we must ensure that they are well prepared.

In addition, the bill also takes major steps towards improving the preparedness of the military to effectively fight terrorism and preventing the proliferation of weapons of mass destruction. We have the best military in the world; however, the war on terrorism is unlike any we've ever fought, and enhancement of current training is important.

Mr. Speaker, I believe that we have produced a good bill. This legislation addresses many real needs in enhancing the security of the United States. I urge my colleagues to join me in support of the legislation.

HONORING THE DEDICATED SERVICE OF DANIEL HARTER

HON. BART GORDON

OF TENNESSEE

IN THE HOUSE OF REPRESENTATIVES

Thursday, December 20, 2001

Mr. GORDON. Mr. Speaker, I rise today to bid farewell to Daniel Harter, an intern with my office. Daniel has provided a unique perspective along with legal expertise as a member of my staff for the past three months, and became an invaluable resource.